The Office of the National Coordinator for Health Information Technology

2015 Edition Proposed Rule

Modifications to the ONC Health IT Certification Program and the 2015 Edition Health IT Certification Criteria

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Agenda

- An Open and Accessible ONC Health IT Certification Program
- 2015 Edition – Goals, Key Proposals & Draft Test Procedures
- Modifications to the ONC Health IT Certification Program
- Analysis of All 2015 Edition Health IT Certification Criteria
- Certification to the 2015 Edition Use Cases (MU & Beyond)
- Public Comment

An Open and Accessible ONC Health IT Certification Program

Supporting the Broader Care Continuum

- **Current:** Prior editions were adopted with a specific focus on the EHR Incentive Programs

- **Proposed:** A more accessible ONC Health IT Certification Program supportive of:
  - ❑ Diverse health IT systems, including but not limited to EHR technology ("Health IT Module" instead of "EHR Module")
    - Remember that there is no "Complete EHR" certification to the 2015 Edition or future editions
  - ❑ Health IT across the care continuum, including long-term and post acute care settings

Supporting the Broader Care Continuum: How Would It Work?

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The Past (2011 and 2014 Editions)	The Proposed Future (2015 and Future Editions)

• ONC included **policy** that supported the EHR Incentive Programs in its previous Editions
  • Defined the Certified EHR Technology (CEHRT) definition on behalf of CMS
  • Required "meaningful use measurement" criteria
  • Specified the minimum number of clinical quality measures developers must certify to in order to participate in the EHR Incentive Programs
  • Specified criteria as "ambulatory" or "inpatient"
	• ONC does not include **policy** to support the EHR Incentive Programs in its Editions
	  • Each program sets its own requirements (e.g., CMS defines the CEHRT definition in its rule)
	  • ONC's Health IT Certification Program is "agnostic" to settings and programs, but can support many different use cases and needs
	  • This allows ONC's Health IT Certification Program to support multiple program and setting needs, for example:
	  • EHR Incentive Programs
	  • Long-term and post-acute care
	  • Chronic care management
	  • Behavioral health
	  • Other public and private programs

Other Programs Using the ONC Health IT Certification Program

A number of programs currently use or are proposing to use the ONC Health IT Certification Program. Here are a few:

- Physician Self-Referral Law exception and Anti-kickback Statute safe harbor for certain EHR donations
- CMS chronic care management services
- Department of Defense Healthcare Management System Modernization Program
- The Joint Commission for participation as ORYX vendor – eCQMs for hospitals

2015 Edition
Goals, Key Proposals & Draft Test Procedures

Overview of the 2015 Edition Proposed Rule

- Supports HHS-wide goals to achieve better care, smarter spending, and healthier people
- Builds on the foundation established by the 2011 and 2014 Editions and addresses stakeholder feedback
- Supports health IT components necessary to establish an interoperable nationwide health information infrastructure
- Incorporates changes designed to foster innovation, support interoperability across the care continuum, open new market opportunities, and provide more provider and patient choices in electronic health information access and exchange

2015 Edition
Broad Health IT Goals

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INTEROPERABILITY

ACCESS

USER/MARKET RELIABILITY

SUPPORTING THE CARE CONTINUUM

2015 Edition Specific Health IT Goals

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- Improve Interoperability
- Facilitate Data Access and Exchange
- Ensure Privacy and Security Capabilities
- Improve Patient Safety
- Reduce Health Disparities
- Improve the Reliability and Transparency of Certified Health IT
- Use the ONC Health IT Certification Program to Support the Care Continuum
- Support Stage 3 of the EHR Incentive Programs

Standards Adoption

New and updated vocabulary and content standards for the structured recording and exchange of health information

- 2015 Base EHR definition
- Common Clinical Data Set
- Other use cases too! For example:
  - ❑ Public Health
  - ❑ Lab Interoperability

Improve Interoperability

2015 Edition Base EHR Definition

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- Focuses, at a minimum, on the functionalities that all users of certified Health IT should possess
- Ensuring that the minimum functionalities required by the HITECH Act remain in the Base EHR Definition
- The requirements can be met using a combination of certified Health IT Modules

Facilitate Data Access and Exchange

Improve Patient Safety

2015 Base EHR Definition

* red = new to the Base EHR Definition

** privacy and security removed – now conditional certification requirements

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Base EHR Capabilities	Certification Criteria
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics § 170.315(a)(5) Problem List § 170.315(a)(7) Medication List § 170.315(a)(8) Medication Allergy List § 170.315(a)(9) Smoking Status § 170.315(a)(12) Implantable Device List § 170.315(a)(20)
Capacity to provide clinical decision support	Clinical Decision Support § 170.315(a)(10)
Capacity to support physician order entry	Computerized Provider Order Entry (medications, laboratory, or diagnostic imaging) § 170.315(a)(1), (2) or (3)
Capacity to capture and query information relevant to health care quality	Clinical Quality Measures (CQMs) – record and export § 170.315(c)(1)
Capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care § 170.315(b)(1) Data Portability § 170.315(b)(6) Application Access to Common Clinical Data Set § 170.315(g)(7) Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2)

Common Clinical Data Set

- Propose to rename the "Common MU Data Set." This has no substantive impact for certification to the 2014 Edition.
- It includes key health data that should be accessible and available for exchange
- Data according to specified vocabulary standards and code sets, as applicable

Patient name	Lab tests
Sex	Lab values/results
Date of birth	Vital signs
Race	Procedures
Ethnicity	Care team members
Preferred language	Immunizations
Problems	Unique device identifiers for implantable devices
Smoking Status	Assessment and plan of treatment
Medications	Goals
Medication allergies	Health concerns

ONC Interoperability Roadmap Goal

2015-2017

Send, receive, find and use a common clinical data set to improve health and health care quality.

The Common Clinical Data Set and the Consolidated CDA

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Patient name	Lab tests
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Date of birth	Vital signs
Race	Procedures
Ethnicity	Care team members
Preferred language	Immunizations
Smoking Status	Unique device identifiers for implantable devices
Problems	Assessment and plan of treatment
Medications	Goals
Medication allergies	Health concerns

The Consolidated CDA is the "suitcase" for exchanging data. It can carry any of the data in the Common Clinical Data Set. The data included depends on the need (e.g., EHR Incentive Programs requirements).

Common Clinical Data Set
In Action

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Transition of care for a single patient

Data portability for multiple patients

Improve Interoperability

Facilitate Data Access and Exchange

Transitions of Care

- Consolidated CDA Release 2.0
- Testing a Health IT Module to both releases of the Consolidated CDA (Release 1.1 and 2.0) for creation and receiving
- Rigorous testing to ensure that a Health IT Module can: identify valid C-CDA templates; use correct vocabulary standards; detect errors in document, sections, and entry templates; and perform XDM processing
- As we did with the 2014 Edition Release 2, we propose certification for sending and receiving consistent with the Edge Protocol
- Patient matching data with constraints

Improve Interoperability

Facilitate Data Access and Exchange

Data Portability

- Common Clinical Data Set + Other Data
- User-enabled creation of an export summary or summaries
- Formatted to the Consolidated CDA 2.0 for document-template types (CCD, Consultation Note, History and Physical, Progress Note, Care Plan, Transfer Summary, and Referral Note (+ Inpatient - Discharge Summary))
- Configuration (Timeframe, Event, and Location)

Improve Interoperability

Facilitate Data Access and Exchange

Application Access to the Common Clinical Data Set (CCDS)

- Technology certified to this criterion will have to demonstrate a functioning API that can respond to requests for each individual data category included in the CCDS as well as a request for all of the data in CCDS at one time (formatted in Consolidated CDA 2.0 standard)
- In the ***2015 Base EHR Definition***, thus it is required for providers participating in Stage 3 of the EHR Incentive Programs
- It's also part of the ***View, Download, and Transmit to 3rd Party*** criterion, enabling patient access
- This proposed capability is meant to represent a floor, not a ceiling

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Facilitate Data Access and Exchange

Application Access to CCDS

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Requirements

1) Security -- developer demonstrates a trusted connection can be established between source system's API and other software
2) Patient selection – means for an application to query for a patient's record
3) Data -- scope is limited to the data in CCDS per patient and a "get"/read-oriented request. Must support:
   - ❑ Data-category request (response format in XML/JSON)
   - ❑ All data request (response format in accordance with the Consolidated CDA)
4) Documentation
   - ❑ Must include accompanying documentation on technical implementation requirements
   - ❑ Must include terms of use, including developer agreements

Request for Comment

1) How to foster an open ecosystem around APIs
2) Whether additional API capabilities should be required for certification
3) Should the C-CDA 2.0 creation capability be limited to the CCD document template

Improve Interoperability

Facilitate Data Access and Exchange

Patient Safety Proposals

- Patient Matching
- Record and exchange Unique Device Identifiers
- Safety-enhanced Design
  - ❑ A conditional certification requirement for an expanded set of certification criteria compared to the 2014 Edition
  - ❑ Health IT developers must submit information about the user-centered design processes used and applied
- Quality Management System (QMS)
  - ❑ A mandatory requirement for certification of a Health IT Module to the 2015 Edition
  - ❑ Health IT developers must identify the QMS used to develop, test, implement, and maintain capabilities of certified technology.
  - ❑ The identified QMS system must be:
    - Compliant with one established by the federal government, or
    - Mapped to one or more QMS established by the federal government or standards development organizations
  - ❑ Attesting that a QMS was not used is no longer permitted

Improve Patient Safety

Addressing Health Disparities

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Proposed Certification Criteria Capabilities	What the Capabilities Provide
More granular recording and exchange of patient race and ethnicity	Allows providers to better understand health disparities based on race and ethnicity, and improve patient care and health equity.
Recording social, psychological, and behavioral data (e.g., education level, stress, depression, alcohol use, sexual orientation and gender identity)	Allows providers and other stakeholders to better understand how this data can affect health, reduce disparities, and improve patient care and health equity
Exchange of sensitive health information (data segmentation for privacy)	Allows for the exchange of sensitive health information (e.g., behavioral health, substance abuse, and genetic information), in accordance with federal and state privacy laws, for more coordinated and efficient care across the continuum.
Accessibility of health IT	• More transparency on the accessibility standards used in developing health IT • Compatibility of certified health IT with accessibility technology (e.g., JAWS text-to-speech application) • Web content accessibility for viewing capability of VDT

Reduce Health Disparities

Draft Test Procedures

- **ONC has released draft test procedures for the proposed 2015 Edition health IT certification criteria**
  - ❑ Gives more transparency to the testing and certification processes
  - ❑ Health IT developers and all stakeholders have "early access"
- **Outcome-based test procedures**
  - ❑ Streamlined test procedure format focuses on outcomes
  - ❑ Promotes more innovation through less prescriptive testing
- **Public comment**
  - ❑ The comment period for the 2015 Edition Draft Test Procedures is **March 20th, 2015 through June 30th, 2015**
  - ❑ To review and comment, visit: http://healthit.gov/policy-researchers-implementers/2015-edition-draft-test-procedures

Modifications to the ONC Health IT Certification Program

Privacy and Security Certification Approach

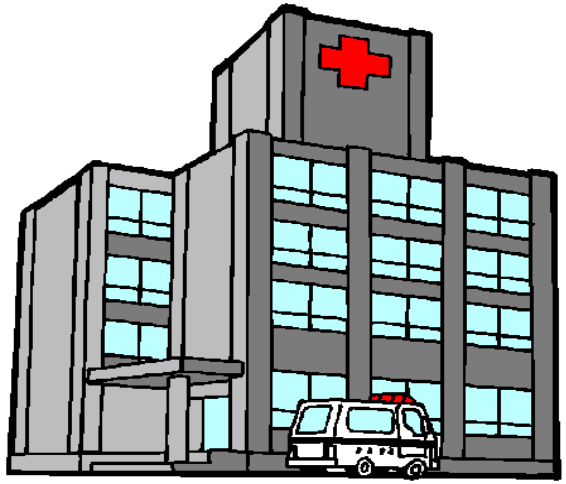
- Health IT developers would need to meet applicable privacy and security certification criteria depending on the other capabilities included in their Health IT Modules

- Removes the responsibility from the provider to ensure that they possess technology certified to all the necessary privacy and security criteria

Ensure Privacy and Security Capabilities

Surveillance of Certified Health IT

- New requirements for "in-the-field" surveillance under the ONC Health IT Certification Program
- ONC-ACBs should ensure that certified Health IT Modules can perform certified capabilities in a production environment (when implemented and used)
  - ❑ Reactive surveillance
  - ❑ Randomized surveillance
- Enhanced surveillance of mandatory transparency requirements



Improve the Reliability and Transparency of Certified Health IT

Improve Patient Safety

Transparency Requirements

- ONC-ACBs must ensure health IT developers disclose:
  - ❑ Broader and more detailed information than is currently required in the 2014 Edition.
  - ❑ Additional types of costs users may incur to implement or use health IT for any purpose within the scope of its certification (not just for achieving MU objectives).
  - ❑ Potential limitations (including contractual restrictions) that would limit a user's ability to implement or use health IT for any purpose within the scope of its certification.
- Health IT developers will be required to attest to voluntarily providing this information:
  - ❑ To customers, prospective customers, and any other person who asks for it (e.g., professional associations representing providers).
  - ❑ To do so timely, in plain writing, and in sufficient detail.

Improve the Reliability and Transparency of Certified Health IT

"Open Data" Certified Health IT Products List (CHPL)

- Converting the CHPL to an open data file to make the reported product data (e.g., test results) more accessible for product analysis
- Propose to require that ONC-Authorized Certification Bodies (ONC-ACBs) report an expanded set of information in the open data file for increased product transparency

Improve the Reliability and Transparency of Certified Health IT

Analysis of All 2015 Edition Health IT Certification Criteria

Certification Program Requirements				
Criteria proposed as always required for 2015 Edition certification (n=2)	Criteria proposed as conditional for 2015 Edition certification depending on capabilities in scope (n= 10)	Proposed 2015 Edition criteria pointed to by CMS for MU 3 & to implement statute (Base EHR definition) (n=37)		Available proposed 2015 Edition criteria for certification (n=19)
Quality Management System - (g)(4)	Authentication, Access Control, Authorization- (d)(1)	CPOE Medications (a)(1)	Patient-specific Education Resources - (a)(17)	Vital Signs, BMI, and Growth Charts - (a)(6)
Accessibility-Centered Design-(g)(8)	Auditable Events and Tamper-resistance- (d)(2)	CPOE Laboratory (a)(2)	Patient Health Information Capture – (a)(19)	Image results - (a)(13)
	Audit Report(s) - (d)(3)	CPOE Diagnostic Imaging (a)(3)	Implantable Device List - (a)(20)	Patient List Creation - (a)(16)
	Amendments - (d)(4)	Drug-drug, Drug-allergy Interaction Checks for CPOE – (a)(4)	Transitions of Care – (b)(1)	eMAR- (a)(18)
	Automatic Access Time-out - (d)(5)	Demographics -- (a)(5)	Clinical Information Reconciliation and Incorporation – (b)(2)	Social, Psychological, and Behavioral Data - (a)(21)
	Emergency Access-(d)(6)	Problem List – (a)(7)	E-Rx - (b)(3)	Decision Support – knowledge artifact - (a)(22)
	End-User Device Encryption-(d)(7)	Medication list – (a)(8)	Data Portability – (b)(6)	Decision Support – service - (a)(23)
	Integrity - (d)(8)	Medication Allergy List – (a)(9)	CQM – record and export - (c)(1)	Incorporate Laboratory Tests and Values/Results – (b)(4)
	Safety Enhanced Design - (g)(3)	CDS – (a)(10)	CQM – import and calculate – (c)(2)	Transmission of Laboratory Test Reports – (b)(5)
	Consolidated CDA Creation Performance – (g)(6)	Drug-formulary and Preferred Drug List Checks –(a)(11)	CQM – report (c)(3)	DS4P – send (b)(7)
		Smoking Status - (a)(12)	VDT - (e)(1)	DS4P – receive (b)(8)
		Family Health History (a)(14); or Family Health History – Pedigree (a)(15)	Secure messaging - (e)(2)	Care Plan - (b)(9)
		Transmission to Immunization Registries (f)(1)	Transmission to PHA – case reporting (f)(5)	CQM filter - (c)(4)
		Transmission to PHA – syndromic surveillance (f)(2)	Transmission to PHA – antimicrobial use and resistance reporting (f)(6)	Accounting of Disclosures – (d)(9)
		Transmission to PHA – reportable laboratory tests and values/results (f)(3)	Transmission to PHA – health care surveys (f)(7)	Accessibility technology compatibility (g)(5)
		Transmission to Cancer Registries (f)(4)	Automated Numerator Recording - (g)(1) or Automated Measure Calculation - (g)(2)	SOAP Transport and Security Specification and XDR/XDM for Direct Messaging – (h)(3)
		Application Access to Common Clinical Data Set – (g)(7)	Direct Project (h)(1) or Direct Project, Edge Protocol, and XDR/XDM (h)(2)	Healthcare Provider Directory – query request (h)(4)
				Healthcare Provider Directory – query response (h)(5)
				Electronic Submission of Medical Documentation– (i)(1)

Green = new to the 2015 Edition

Light Blue = Criteria in the "available" column previously adopted in a certification edition to support MU1/MU2

Red font = "unchanged" criteria (eligible for gap certification)

Blue font = "minimally revised" criteria

Certification Responsibilities for Health IT Developers

IF you seek product certification to the following:	THEN your product will always need to be certified to:	AND will also need to be certified to:
Any clinical criterion in 45 CFR 170.315(a)	• The privacy & security (P&S) criteria at § 170.315(d)(1)-(d)(7) • Quality management system (QMS) at § 170.315(g)(4) • Accessibility-centered design (ACD) at § 170.315(g)(8)	Safety-enhanced design (SED) at § 170.315(g)(3) if you seek certification to any one of the following criteria: • § 170.315(a)(1)-(10), (18), (20), (22), and (23)
Any care coordination criterion in 45 CFR 170.315(b)	• The P&S criteria at § 170.315(d)(1)-(d)(3) and (d)(5) - (d)(8) • QMS at § 170.315(g)(4) and ACD at (g)(8)	SED at § 170.315(g)(3) if you seek certification to any one of the following criteria: • § 170.315(b)(2)-(b)(4) Consolidated CDA performance at § 170.315(g)(6) if you seek certification to any one of the following criteria: • § 170.315(b)(1), (2), (6), (7), and (9)
Any clinical quality measures criterion in 45 CFR 170.315(c)	• The P&S criteria at § 170.315(d)(1)-(d)(3) • QMS at § 170.315(g)(4) and ACD at (g)(8)	N/A
Any privacy and security criterion in 45 CFR 170.315(d)	• QMS at § 170.315(g)(4) • ACD at § 170.315(g)(8)	N/A
Any patient engagement criterion in 45 CFR 170.315(e)	• The P&S criteria at § 170.315(d)(1)-(d)(3), (d)(5), and (d)(7) • QMS at § 170.315(g)(4) and ACD at (g)(8)	Consolidated CDA performance at § 170.315(g)(6) if you seek certification to § 170.315(e)(1)
Any public health criterion in 45 CFR 170.315(f)	• The P&S criteria at § 170.315(d)(1)-(d)(3) and (d)(7) • QMS at § 170.315(g)(4) and ACD at (g)(8)	N/A
45 CFR 170.315(g)(1) or (2)	• QMS at § 170.315(g)(4)	N/A
45 CFR 170.315(g)(7)	• QMS at § 170.315(g)(4) and ACD at (g)(8)	Consolidated CDA performance at § 170.315(g)(6)
Any transport methods and other protocols criterion in 45 CFR 170.315(h)	• The P&S criteria at § 170.315(d)(1)-(d)(3) • QMS at § 170.315(g)(4) and ACD at (g)(8)	Transitions of care at § 170.315(b)(1) if you seek certification to § 170.315(h)(1)
Any administrative criterion in 45 CFR 170.315(i)	• The P&S criteria at § 170.315(d)(1)-(d)(3) and (d)(5)-(d)(8) • QMS at § 170.315(g)(4) and ACD at (g)(8)	Consolidated CDA performance at § 170.315(g)(6) if you seek certification to § 170.315(i)(1)

2015 Edition "Unchanged" Criteria Associated with MU Stage 3

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Ambulatory & Inpatient	
CPOE - medications	Automatic access time-out
CPOE – diagnostic imaging	Emergency access
Medication list	End-user device encryption
Medication allergy list	Integrity
Clinical quality measures – report**	Secure messaging*
Authentication, access control, and authorization	Direct Project
Auditable events and tamper-resistance	Direct Project, Edge Protocol, and XDR/XDM
Audit report(s)	Quality Management System^
Amendments	

These certification criteria would be eligible for gap certification.

* The secure messaging criterion is unchanged compared to the 2014 Edition version. It was required for EPs in Stage 2, but not for EH/CAHs. In Stage 3, it is proposed to be required for both EPs and EH/CAHs.

** This criterion was proposed in the 2016 IPPS NPRM for program alignment.

^ It may be unchanged or revised depending on how the product was previously certified.

2015 Edition "Unchanged" Criteria NOT Associated with MU Stage 3

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Ambulatory & Inpatient	
Image results	Accounting of disclosures
Patient list creation	SOAP Transport and Security Specification
Electronic medication administration record	

These certification criteria would be eligible for gap certification.

Delta's between the 2014 Edition & proposed 2015 Edition

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2014 Edition	2015 Edition Difference
• Quality management system	• Removed option to meet the criterion by attesting to using "no" QMS.
• All privacy and security criteria	• Wording clarifications, but no substantive changes
• Safety-enhanced design	• Expanded list of applicable certification criteria

Delta's between the 2014 Edition & proposed 2015 Edition, continued

2014 Edition	2015 Edition Difference
• CPOE – Medications	• None
• CPOE – Laboratory	• Added LOI IG and eDOS IG
• CPOE – Diagnostic Imaging	• None
• Drug-drug/drug-allergy interaction checks for CPOE	• Added interaction check response documentation (record at least one action taken and by whom)
• Demographics	• Changed preferred language to RFC 5646; expanded value sets for race/ethnicity; record sex per HL7 v3

Delta's between the 2014 Edition & proposed 2015 Edition, continued

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2014 Edition	2015 Edition Difference
• Vital Signs (not associated with Stage 3)	• Added additional vital signs; record vital signs according to LOINC and UCUM; record metadata; offer optional certification, including for pediatrics
• Problem List	• Set baseline as the most recent version of SNOMED CT

Delta's between the 2014 Edition & proposed 2015 Edition, continued

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2014 Edition	2015 Edition Difference
• Clinical Decision Support	• Updated Infobutton standards; Added interaction check response documentation (record at least one action taken and by whom)
• Drug-formulary and preferred drug list checks	• Adopt NCPDP Formulary and Benefit Standard v3.0 (if drug-formulary); auto-check whether DF or PDL exists for patient and medication; indicate last update of DF of PDL
• Smoking status	• Record, change, and access smoking status in any SNOMED CT code (but must be able to exchange using 8 specified SNOMED CT codes)

Delta's between the 2014 Edition & proposed 2015 Edition, continued

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2014 Edition	2015 Edition Difference
• Family health history	• Updated SNOMED CT
• Family health history – pedigree	• HL7 Pedigree standard and HL7 Pedigree IG
• Patient-specific education resources	• Only require Infobutton; updated Infobutton standards; do not have to use Infobutton for lab values/results; request resources based on patient's preferred language
• Transitions of care	• Refer to description of proposal in previous slides
• Data portability	• Refer to description of proposal in previous slides

Delta's between the 2014 Edition & proposed 2015 Edition, continued

2014 Edition	2015 Edition Difference
• Clinical information reconciliation and incorporation	• Reconcile problem, med, med allergy data from valid C-CDAs (Releases 1.1 and 2.0); generate conformant C-CDA based on reconciled info
• E-prescribing (e-Rx)	• Expand e-Rx transactions; ability to codify e-Rx instructions in structured Sig format; e-prescribe all meds in metric unit standard
• View, download, and transmit to 3rd party	• Updated C-CDA R2; updated Common Clinical Data Set; make diagnostic imaging reports available for patient certification; require API access capabilities (similar to App Access to CCDS); add "addressee" to activity history log; provide lab reports in compliance with CLIA

Delta's between the 2014 Edition & proposed 2015 Edition, continued

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2014 Edition	2015 Edition Difference
	• For all CQM criteria – comment solicitation on the versions of standards to adopt
• CQMs – record and export	• User "on demand" ability to export data
• CQMs – import and calculate	• User "on demand" ability to import data; "closed" systems must demonstrate import capability; intent to test import of larger # of test records

Delta's between the 2014 Edition & proposed 2015 Edition, continued

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2014 Edition	2015 Edition Difference
• Transmission to immunization registries	• Updated IG; require NDC codes for recording administered vaccines; require bi-directional exchange (display history and forecast from registry)
• Transmission to PHA – syndromic surveillance	• Updated IG for inpatient settings; allow any electronic method for ambulatory settings
• Transmission to PHA – reportable lab tests & values/results	• Updated SNOMED CT; updated LOINC; updated HL7 IG
• Transmission to cancer registries	• Updated SNOMED CT; updated LOINC; updated HL7 IG

Delta's between the 2014 Edition & proposed 2015 Edition, continued

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2014 Edition	2015 Edition Difference
• Incorporate lab tests and values/results (not associated with Stage 3) • Transmit lab test reports (not associated with Stage 3)	• (For both criteria) Adopt HL7 Lab Results Interface IG (Release 2); display test report info in compliance with CLIA; updated LOINC • For incorporate lab tests only – solicit comment on HL7 EHR-S Functional Requirements standard
• Auto numerator recording and auto measure calculation	• Will be revised to align with Stage 3 objectives and measures

"New" Certification Criteria for Stage 3

Proposed Criterion	Proposed Functionality and Standards
• Patient health information capture	• **Record and access patient health info documents (with a link to access)** • **Record info shared by patients**
• Implantable device list	• **Record, change, and access Unique Device Identifier(s)** • **Parse UDI data elements** • **Retrieve and provide user access to device description from Global Unique Device Identification Database and parsed data elements**
• Application access to Common Clinical Data Set	• **Refer to description of proposal in previous slides**

"New" Certification Criteria for Stage 3 (continued)

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Proposed Criterion	Proposed Functionality and Standards
• Consolidated CDA Creation Performance	• **Create a data file in accordance with C-CDA Release 1.1 and Release 2.0 that matches a gold-standard, reference file** • **Must be able to create document templates (CCD, Consultation Note, History and Physical, Progress Note, Care Plan, Transfer Summary, Referral Note, and (inpatient only) Discharge Summary)** • **Must conform to vocabulary standards and value sets adopted in C-CDA Releases 1.1 and 2.0**

"New" Certification Criteria for Stage 3 (continued)

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Proposed Criterion	Proposed Functionality and Standards
• Accessibility-centered design	• **Identify whether and which accessibility-centered standard or law was used in the development, testing, implementation, and maintenance of any criterion presented for certification**
• Transmission to PHAs – case reporting	• **IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture**
• Transmission to PHAs – antimicrobial use and resistance reporting	• **Select sections of the HL7 IG for C-CDA R2: Healthcare Associated Infection Reports, Release 1**
• Transmission to PHAs – health care surveys	• **HL7 IG for C-CDA R2: National Health Care Surveys, Release 1, DSTU**

"New" Certification Criteria Not Tied to Stage 3

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Proposed Criterion	Proposed Functionality and Standards
• Social, psychological, and behavioral data	• **Enable user to record, change, access data (e.g., SOGI, education, depression, physical activity) using SNOMED CT and LOINC codes**
• Decision support – knowledge artifact	• **Enable user to send and receive CDS artifacts using HL7 V3: CDS Knowledge Artifacts Specification, Release 1.2, DSTU**
• Decision support – service	• **Enable a user to send and receive CDS using HL7 IG: Decision Support Service, Release 1.1, DSTU**
• Care Plan	• **Enable a user to record, change, access, create and receive care plan info using the Care Plan document template in the C-CDA R2**

"New" Certification Criteria Not Tied to Stage 3, continued

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Proposed Criterion	Proposed Functionality and Standards
• Data segmentation for privacy – send	• **Enable user to create summary record (in accordance with C-CDA Releases 1.1 and 2.0) tagged as restricted and subject to re-disclosure restrictions in HL7 IG: DS4P, Release 1**
• Data segmentation for privacy – receive	• **Enable user to receive summary care record in accordance with HL7 IG: DS4P, Release 1** • **Apply document-level tagging and sequester document** • **Allow user to view document**
• Clinical quality measures - filter	• **Record data and filter CQM results (patient and aggregate levels) by provider and patient characteristics (e.g., TIN, NPI, patient age)**

"New" Certification Criteria Not Tied to Stage 3, continued

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Proposed Criterion	Proposed Functionality and Standards
• Accessibility technology compatibility	• **For any clinical (a), care coordination (b), or patient engagement (e) criterion presented for certification, demonstrate compatibility with at least one text-to-speech technology**
• Healthcare provider directory - query request • Healthcare provider directory - query response	• **Request or respond to queries for individual, organizational, both individual and organizational providers, relationships between providers using IHE Healthcare Provide Directory, Trial Implementation** • **Optional – process or make federated queries**

"New" Certification Criteria Not Tied to Stage 3, continued

Proposed Criterion	Proposed Functionality and Standards
• Electronic submission of medical documentation	• **Create electronic documents formatted to C-CDA R2 and HL7 IG for C-CDA R2: Additional CDA R2 Templates – Clinical Documents for Payers – Set 1, Release 1** • **Apply and validate digital signature using HL7 IG for CDA R 2: Digital Signatures and Delegations of Rights, Release 1** • **Apply digital signature to single or bundles of documents using Author of Record Level 1: IG** • **Apply digital signature as accompanying metadata using Provider Profiles Authentication: Registration IG**

Certification to the 2015 Edition Use Cases (MU & Beyond)

Proposed EHR Incentive Programs
Stage 3 Meaningful Use Objectives

- **Objective 1:** Protect Patient Health Information
- **Objective 2:** Electronic Prescribing
- **Objective 3:** Clinical Decision Support
- **Objective 4:** Computerized Provider Order Entry
- **Objective 5:** Patient Electronic Access to Health Information
- **Objective 6:** Coordination of Care through Patient Engagement
- **Objective 7:** Health Information Exchange
- **Objective 8:** Public Health and Clinical Data Registry Reporting

Certified Health IT Module(s) to Support the EHR Incentive Programs Stage 3

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Certification Criteria to Support Meeting Specific Objectives

- (Objective 5 only) Patient-specific Education Resources
- (Objectives 5 & 6) View, Download, & Transmit to 3rd Party; and API Access to CCDS
- (Objective 6 only) Secure Messaging
- (Objective 7) Transitions of Care; and Clinical Information Reconciliation & Incorp
- (Objective 8) "Public Health" (EP: choose 3 of 7, EH/CAH: choose 4 of 7)
- (Objective 2) e-Prescribing; and Drug-formulary Checks
- (Objective 3) Clinical Decision Support; and Drug-drug, Drug-allergy Interaction Checks
- (Objective 4) Computerized Provider Order Entry

CEHRT Definition Requirements

- Family Health History (choose 1 of 2)
- Import and Calculate; and Report CQMs
- Patient Health Information Capture (and supports Objective 6)

CEHRT Definition Requirements

- Meaningful Use Measurement Capabilities/Certification Criteria

Conditional Certification Requirements

- Privacy & Security
- Safety-enhanced Design
- CCDA Creation Performance

Mandatory Certification Requirements

- Quality Management System
- Accessibility-centered Design

Base EHR Definition

- Base EHR Capabilities/Certification Criteria

Support Stage 3 of the EHR Incentive Programs

What is Minimally Required for Stage 3?

2014 Edition vs. Proposed 2015 Edition

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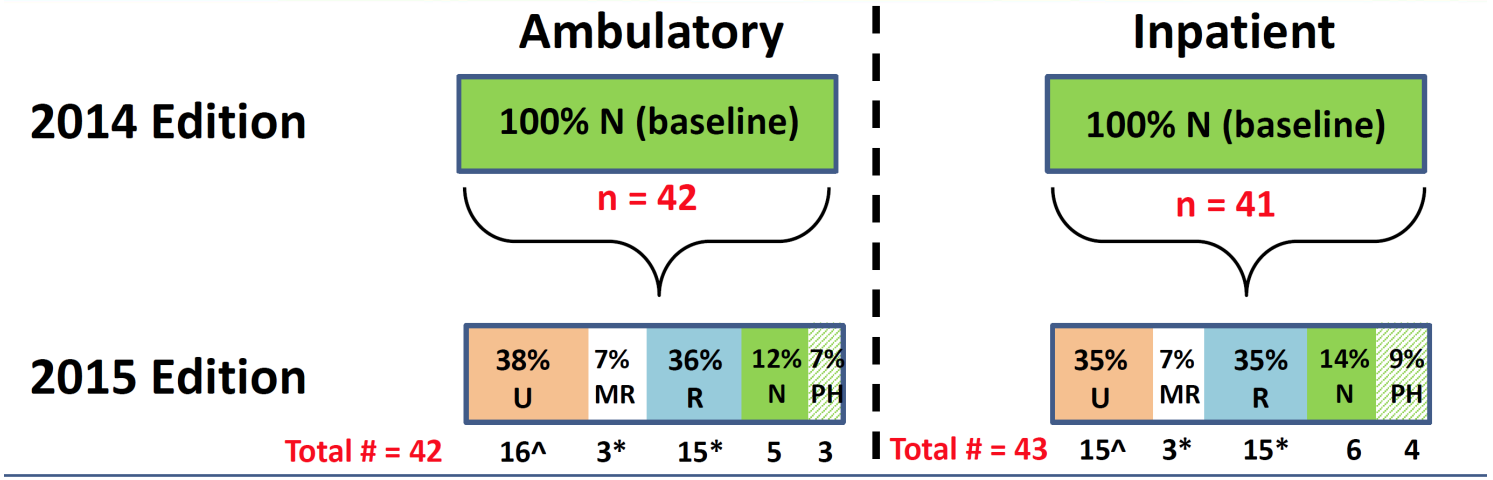

Bottom Line

- 45% of criteria are unchanged or minimally revised for the ambulatory setting.
- 42% of criteria are unchanged or minimally revised for the inpatient setting.
- Only need to do ~60% of the proposed 2015 Edition criteria to participate in Stage 3.
- The total minimum number of criteria needed to participate in Stage 3 remains the same for EPs and almost the same for EHs/CAHs as compared to Stage 2.
  - **Note:** This analysis does not account for potential exclusions

U = Unchanged criteria
MR = Minimally revised criteria
R = Revised criteria
N = New criteria

PH = Public health criteria (new and revised. EPs choose 3 of 6 measures and EHs/CAHs choose 4 of 6 measures.
^ Includes the "QMS" criterion, which may be revised for some health IT developers
* Depends on which family health history criterion is chosen (SNOMED CT or pedigree)

Certified Health IT Module(s) to Support Other Health Care Settings (LTPAC Example)

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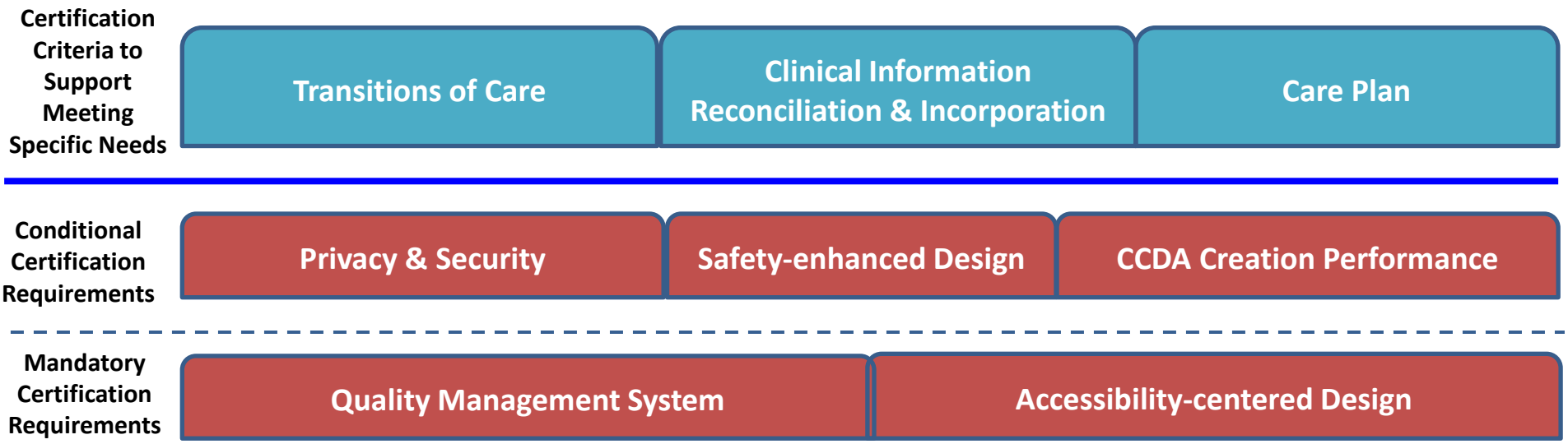
Long-Term Post-Acute Care Certification (example only)



Use of the Health IT Certification Program across the care continuum

Certified Health IT Module(s) to Support Other Health Care Settings (Behavioral Health Example)

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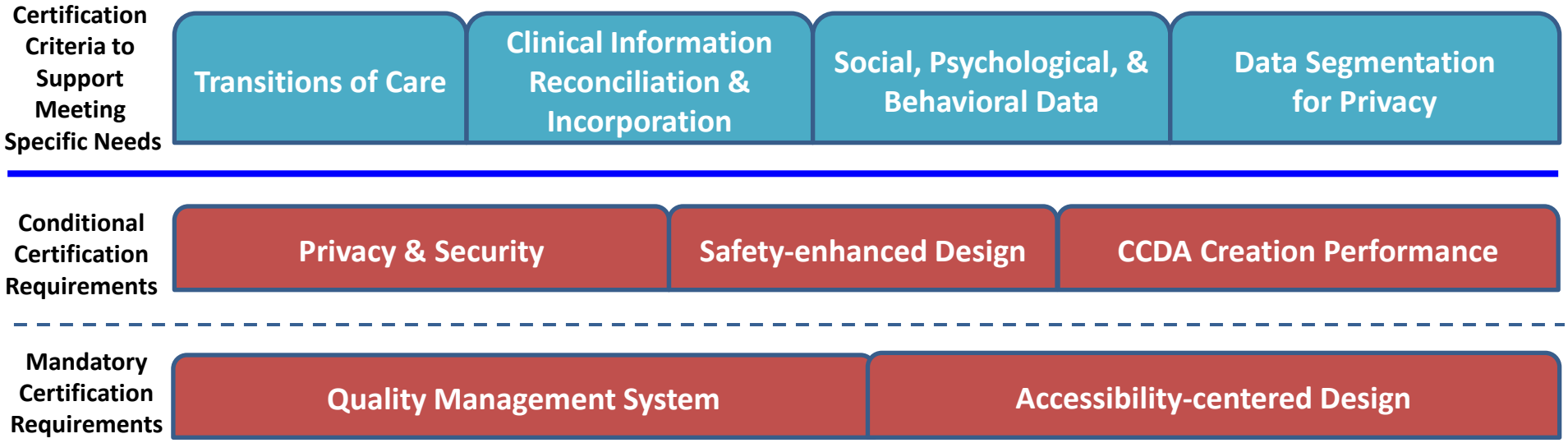
Behavioral Health Certification (example only)



Use of the ONC Health IT Certification Program to Support the Care Continuum

Public Comment

When and How to Comment

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- ONC published the 2015 Edition Proposed Rule in the Federal Register on **March 30, 2015**
- The comment period is open until **May 29, 2015**
- You can review the proposed rule and comment here: http://www.regulations.gov/#!documentDetail;D=HHS_FRDOC_0001-0572
- To assist in commenting on the rule, ONC provides a:
  - ❑ Microsoft Word version of the rule (http://www.healthit.gov/sites/default/files/2015_editionnprm_ofr_disclaimer_3-20-15.docx); and
  - ❑ Public Comment Template (http://www.healthit.gov/sites/default/files/2015editionnprm_public_comment_template_4-1-15_final508_.docx)

Additional Resources

- Press release: http://www.healthit.gov/sites/default/files/HHS_Proposes_Rules_Path_Inop_FINAL_FORMATTED.docx

- Fact sheet: http://www.healthit.gov/sites/default/files/ONC-Certification-Program-2015-Edition_FactSheet.pdf

- ONC regulations: http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations

QUESTIONS?